DRAFT RECOMMENDATIONS REGARDING INFORMED CONSENT AND WAIVER OF CONSENT

Revised version from SACHRP, October 9, 2012

Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Sebelius:

In accordance with the provisions of the charter for the Secretary's Advisory Committee on Human Research Protections (SACHRP), I respectfully submit for your consideration a recommendation relative to Department of Health and Human Services Regulation for the Protection of Human Subjects as codified in 45 CFR Part 46. This letter represents the xxx in a series of recommendations from SACHRP.

The informed consent requirements found in HHS 45 CFR 46 Regulation for the Protection of Human Subjects in Research provide a bedrock protection for individuals participating in research studies. While the regulatory default for non-exempt research is to obtain and document the informed consent of all participants, the regulations anticipated scenarios where this default requirement would be inappropriate given the proposed research methods, the context in which the research would be conducted or the subject population. The regulations included provisions allowing IRBs to waive some or all elements of informed consent when specific conditions have been met.

In practice, the regulations governing waivers of informed consent at §46.116(d) are constructed in such a way that many IRBs require investigators to include information in consent documents that adds little or no value to the consent process, for example, a statement that "the only alternative is not to participate in this research." In fact, by adding length to consent documents and including irrelevant information it could be argued that the effectiveness of the consent process is diminished. In addition, IRBs struggle to interpret whether and how the criteria should be applied in order to grant a full waiver of informed consent.

SACHRP proposes modification of 45 CFR Part 46.116 in order to: (1) reorganize the elements of informed consent at §116 (a) and (b); (2) empower IRBs to waive selected elements of consent when they deem appropriate; and (3) clarify the circumstances in which an IRB may grant a complete waiver of informed consent.

The proposed restructuring of 45 CFR Part 46.116 would not erode the ethical foundation embodied in informed consent. Modification of the regulations would instead permit IRBs to more appropriately grant partial or complete waivers of informed consent without impinging on the ethical validity of the consent process or the research itself. These waivers are already permitted in the existing regulations, but nuances in the language have deterred IRBs from exercising the flexibility that the regulations were intended to provide.

Therefore, SACHRP recommends the following new language for inclusion in 45 CFR 46. Note that FDA regulations (21 CFR 50) do not provide for an analogous waiver of informed consent; to the extent that the elements below are also found in FDA requirements for informed consent, the same recommendations should be considered.

§46.116 General requirements for informed consent.
Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

In considering the elements of informed consent to be provided to subjects, the focus should be on those activities, risks and benefits that are specific to the research (as distinguished from the activities, risks and benefits that subjects would experience if not participating in the research)

(a) Except when waived under paragraphs (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

> *(1) A statement that the study involves research, an explanation of the purposes of the research, a description of research-related activities with emphasis on those activities that are directly relevant to an informed decision to participate, and identification of any activities that are experimental;*
> *(2) A description of those foreseeable risks or discomforts about which a reasonable potential subject would want to know due to the probability or seriousness of their occurrence;*
> *(3) A description of any benefits to the subject or to others which may reasonably be expected from the research; if there are no direct benefits expected for subjects, this should be stated;*
> *(4) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights; and*
> *(5) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subjects is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.*

(b) When the IRB determines that one or more of the following elements of information are material to prospective subjects' decisions to participate, the elements shall be provided to each subject. In the event one or more of the following elements is not to be included, it is not necessary to determine or document that the waiver criteria under paragraph (c) or (d) of this section are met:

> *(1) A disclosure of appropriate alternative procedures or courses of treatment, that might be advantageous to the subject;*
> *(2) A statement describing the extent to which confidentiality of records identifying the subject will be maintained;*
> *(3) A statement of whether compensation, medical treatment, or payment for that medical treatment is available if injury occurs, where further information may be obtained, and whom to contact in the event of a research-related injury to the subject.*
> *(4) A statement that the research may involve risks that are currently unforeseeable;*

(5) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
(6) Any additional costs to the subject that may result from participation in the research;
(7) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(8) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
(9) The approximate number of subjects involved in the study; and
(10)The expected duration of the subject's participation.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the basic elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designated to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
(2) The research could not reasonably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the basic elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research, or the component of the research related to the proposed waiver or alteration of consent, involves no more than minimal risk to the subjects. When the request for a waiver involves access to materials (e.g. data, documents, records or specimens) the IRB should consider the following:

a. the minimum necessary information to accomplish the research, including the need for identifiers;
b. the sensitivity of the information; and
c. the provisions in place to protect confidentiality;

(2) The research could not reasonably be carried out without the waiver or alteration. Appropriate ethical or scientific rationales might include, for example: (i) scientific validity would be compromised if consent were required because it would introduce bias to the sample selection; or (ii) subjects' behaviors or responses would be altered, such that study conclusions would be biased; or (iii) the consent procedure would itself create additional threats to privacy that would otherwise not exist; or (iv) there is risk of inflicting significant psychological, social or other harm by contacting individuals or families. Once the IRB has determined that the waiver or alteration does not adversely impact the ethical nature or scientific rigor of the research, logistical issues (e.g. cost, convenience, speed) may be considered; and

(3) When appropriate, subjects will be provided with previously undisclosed information about the nature of the study following their participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted or required to do so under applicable federal, state, or local law.